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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV (1417YP1044)	1329
7590	09/30/2005		EXAMINER MOHANDESI, JILA M	
Matthew J. Gryzlo, Esq. Wallenstein Wagner & Rockey, Ltd. 311 S. Wacker Drive, 53rd Floor Chicago, IL 60606-6630			ART UNIT 3728	PAPER NUMBER

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Full

Office Action Summary	Application No.	Applicant(s)	
	10/779,993	LEWIS ET AL.	
	Examiner	Art Unit	
	Jila M. Mohandesi	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claim 14-21 drawn to an invention nonelected with traverse in Paper filed on November 08, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Declaration

2. The declaration under 37 CFR 1.132 filed July 14, 2005 is sufficient to overcome the rejection of claims 1-13 under 35 U.S.C. 102 (e), based upon the U.S. Patent Application Publication No. 2002/01245266 (Lewis).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361) in view of Sano et al. (6,326,010). Johnson '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, and seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container. See

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Figures 1 and 2 embodiments and column 1, lines 11-21. Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs and plasma. Sano '010 discloses that Albumin, particularly human serum albumin, is a protein mostly included in blood plasma. Sono '010 also discloses that it is desirable to store albumin a sterilized plastic vessel. Based on the teaching of Sono'010 that albumin is included in plasma and Johnston '361 discloses storing plasma in the flexible bags, it would have been obvious to one of ordinary skill in the art at the time the invention was made to also store albumin in the flexible bags of Johnson '361.

With respect to claims 5 and 8, see column 6, lines 57-61.

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

With respect to claim 2 official notice is taken that it is old and conventional to mix albumin with sterilized water and stabilizers.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as modified above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitations of the claims except for it are silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

Response to Arguments

7. Applicant's arguments see the declaration filed July 14, 2005, with respect to claims 1-13 have been fully considered and are persuasive. The rejection under U.S.C. 102 (e) of claims 1-13 has been withdrawn.

8. Applicant's arguments filed July 14, 2005 with respect to the rejection under U.S.C. 103 (a) have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

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where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the above references are both directed to containers being utilized in the medical industry.

In response to applicant's argument that the two cited references are not properly combinable, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that Johnson does not specifically teach that albumin could be packaged in a flexible polymeric container, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M. Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

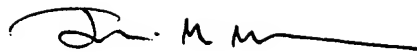
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jila M Mohandesi

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**JILA M. MOHANDESI
PRIMARY EXAMINER**

Primary Examiner
Art Unit 3728

JMM

September 29, 2005